

FIG. 1

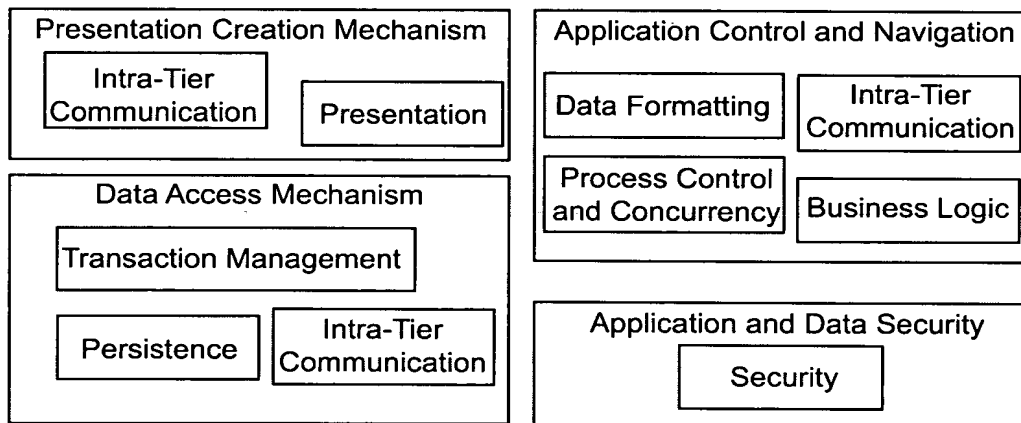
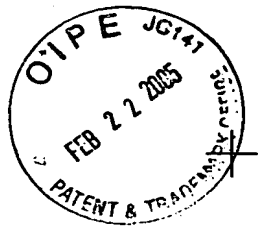


FIG. 2

+



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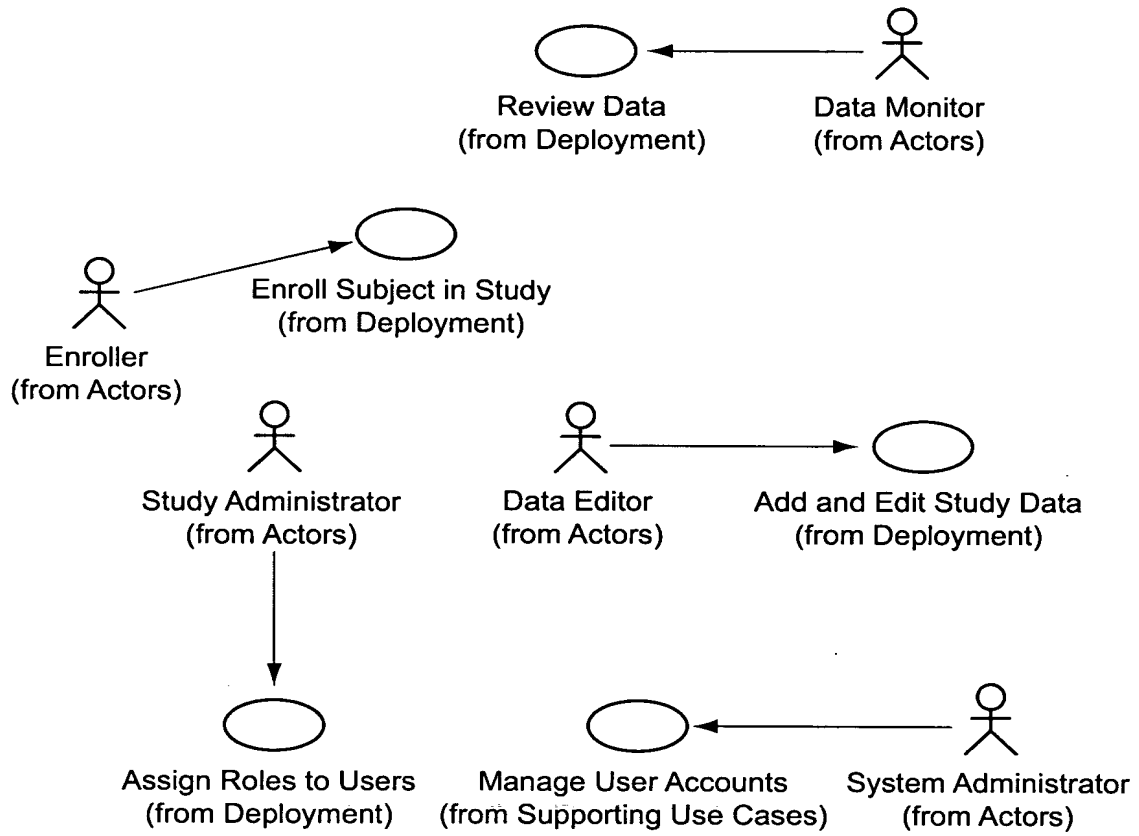
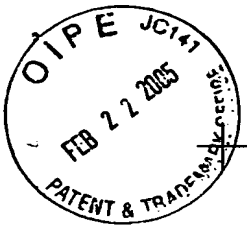


FIG. 3

+



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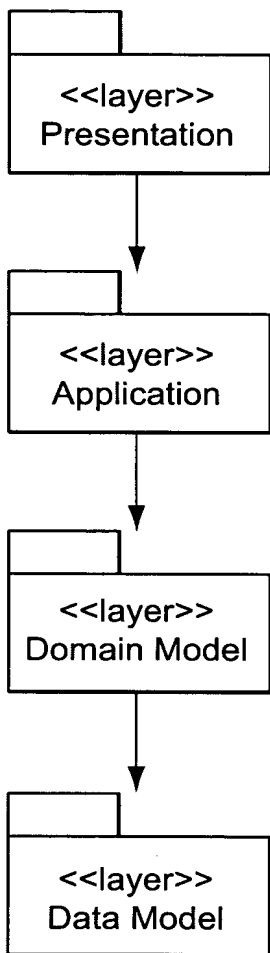
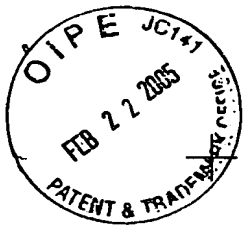


FIG. 4

+



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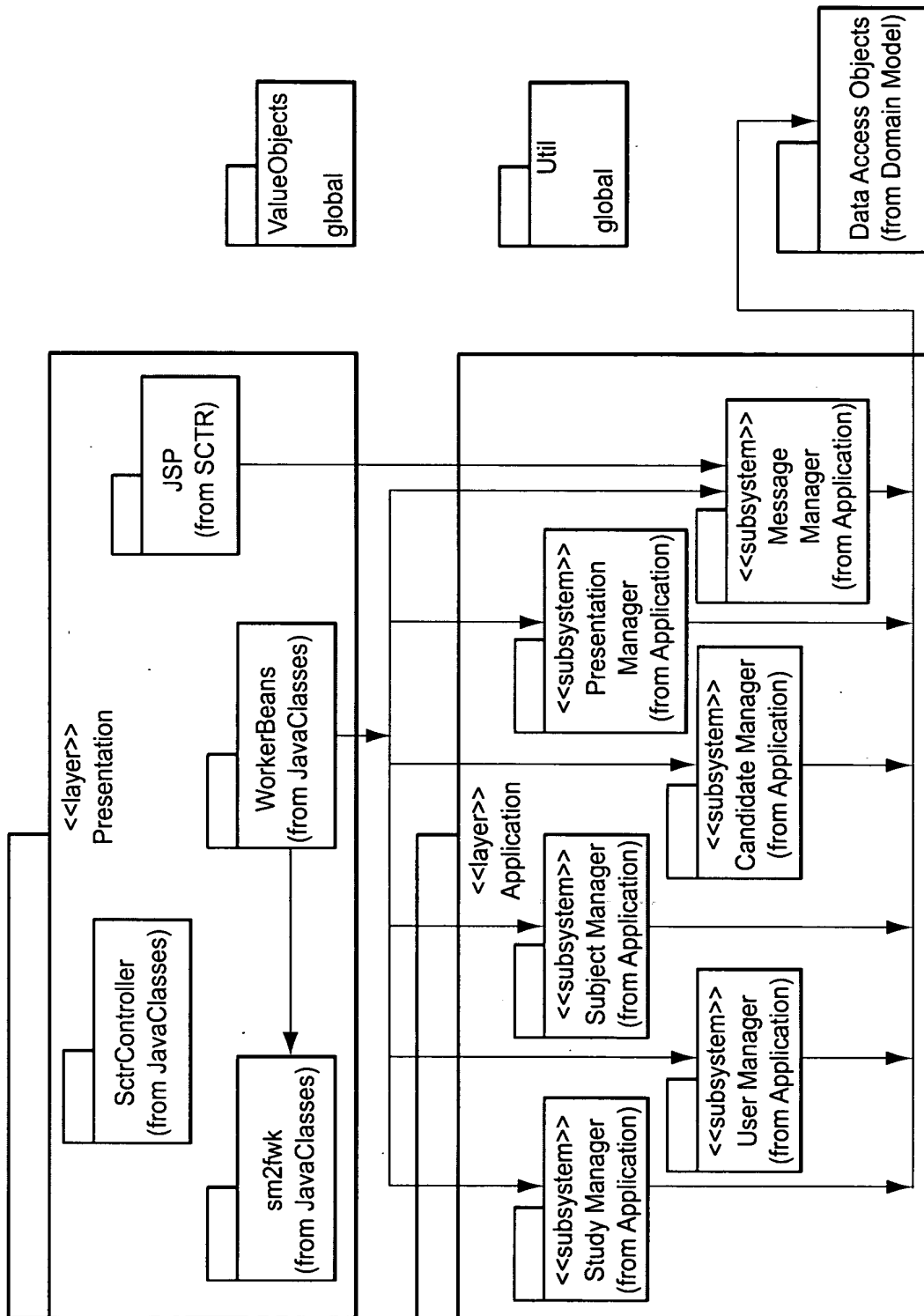
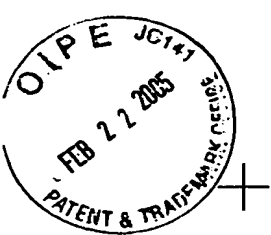


FIG. 5

+



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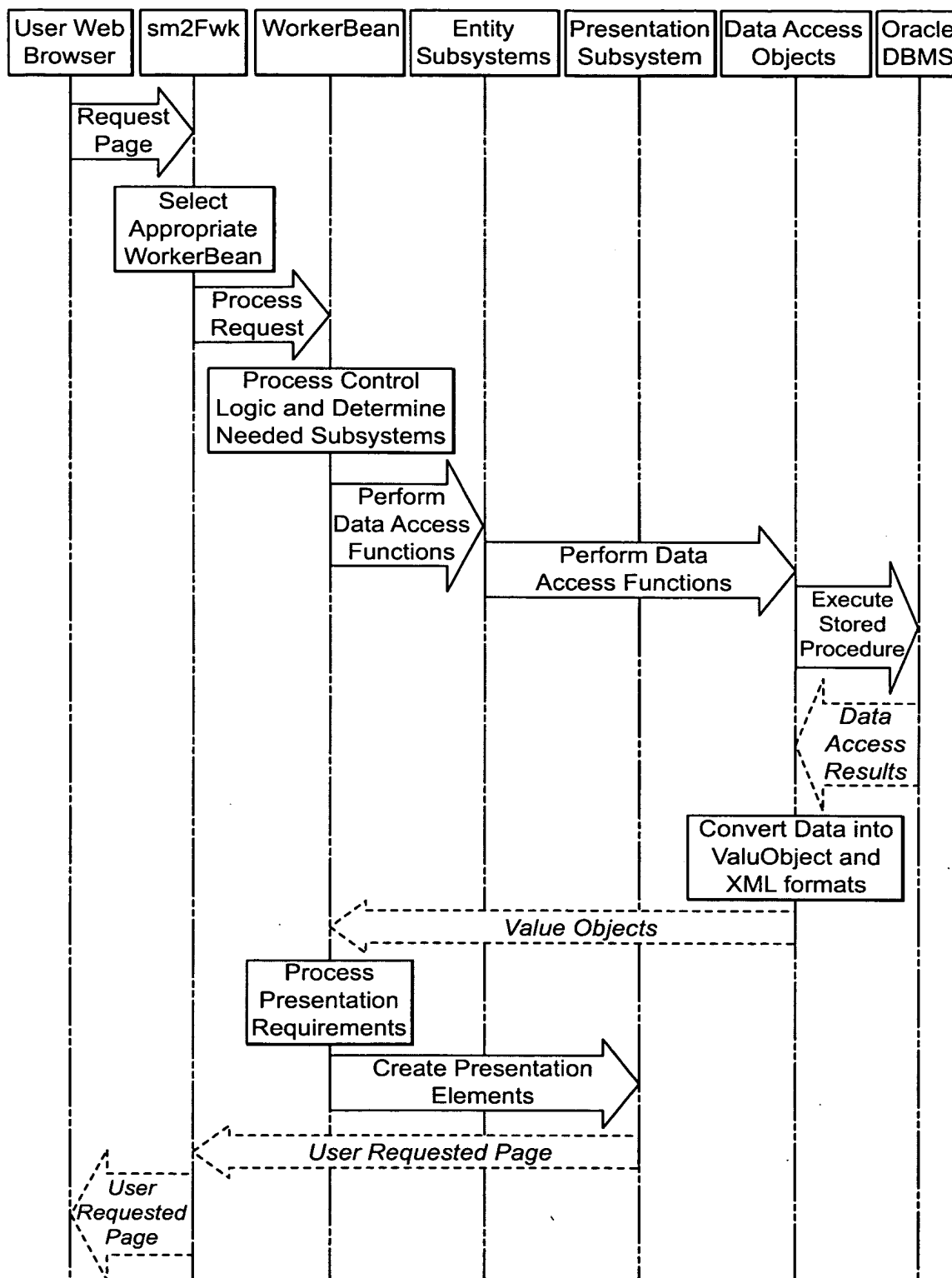
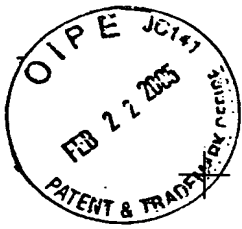


FIG. 6



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Login Function

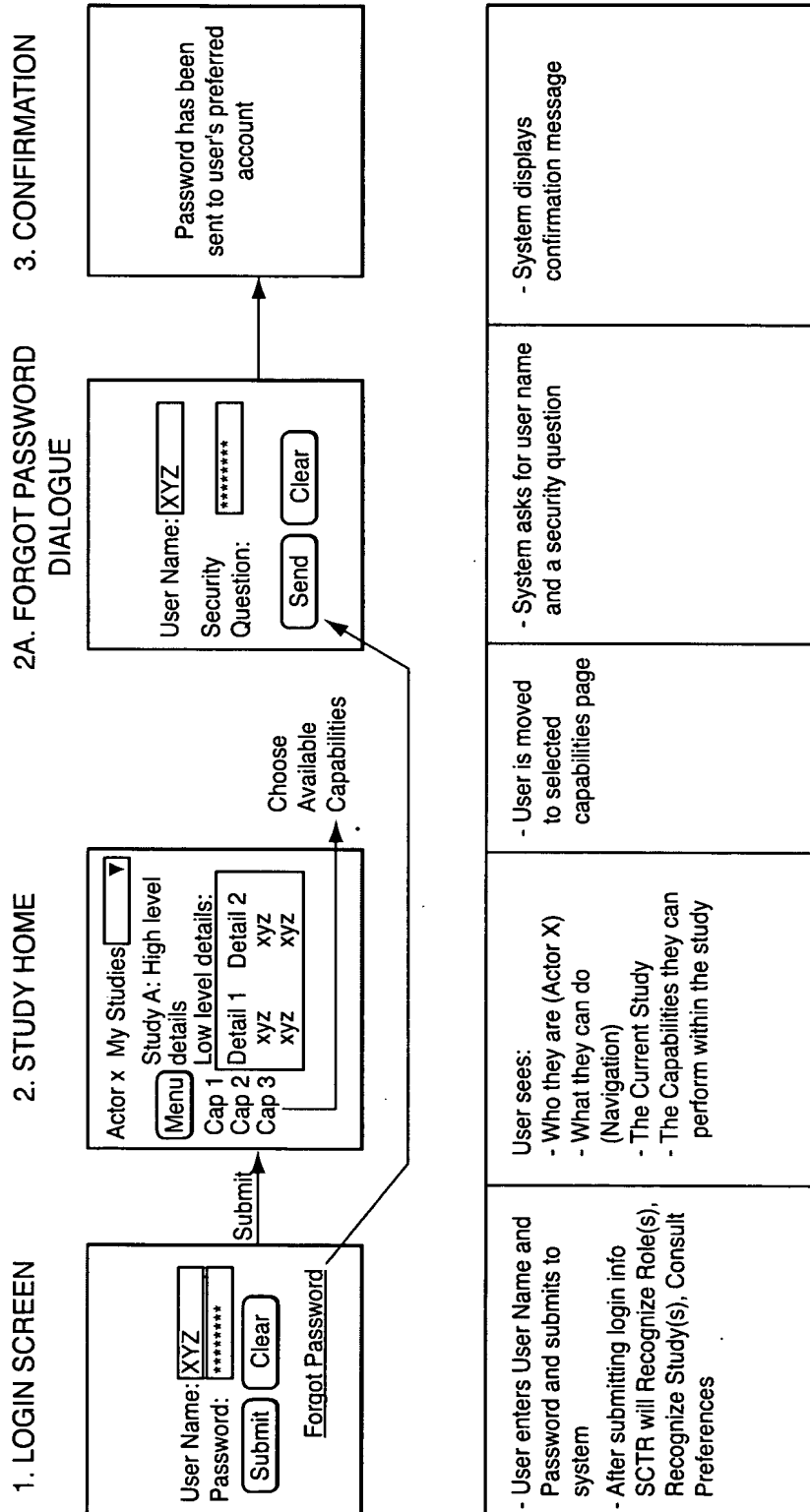


FIG. 7

+

Register Candidate Subject Function

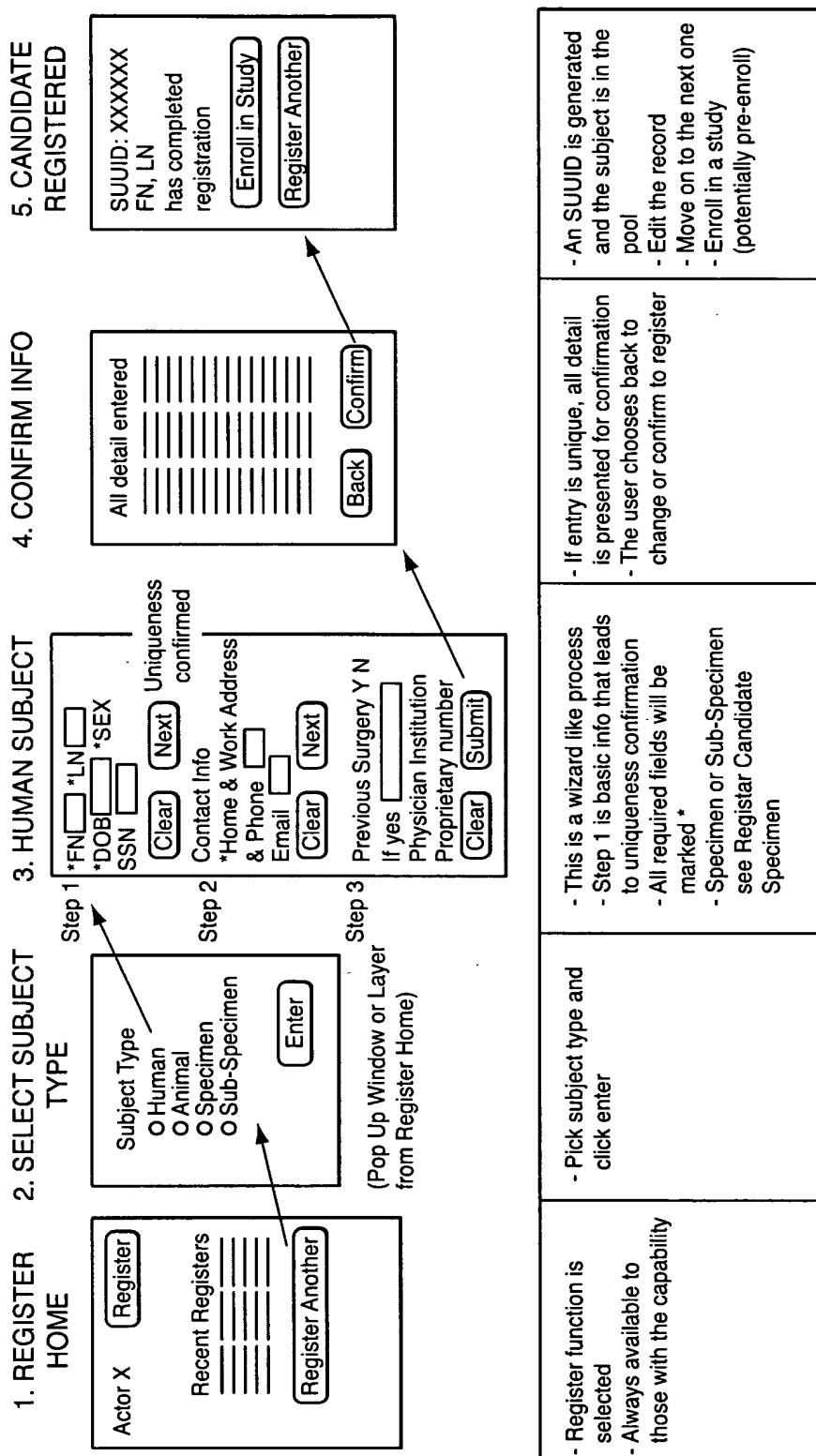
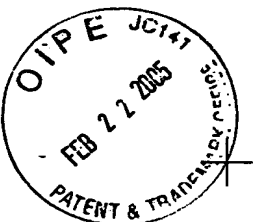


FIG. 9



Register Specimen Function

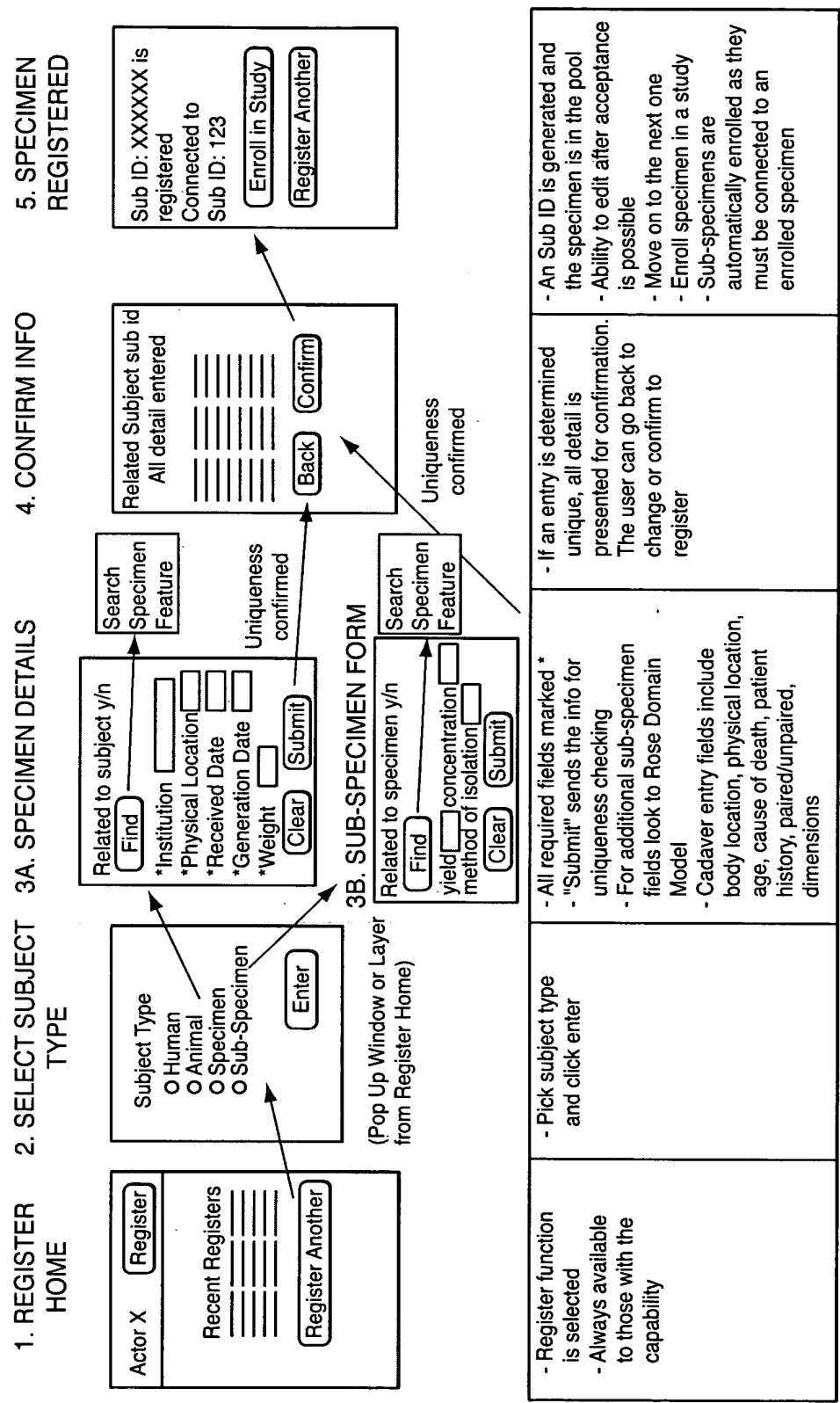
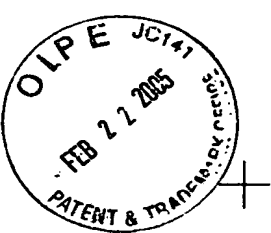


FIG. 10



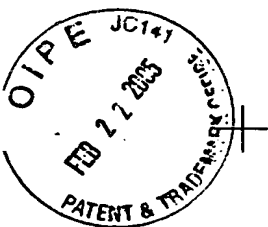


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ADVANCED SEARCH

Who I Am	Search (Easy, Advanced)
Where I Am	
<div>Advanced Search</div>	
Keywords:	
<hr/>	
PATIENT:	
SUUID:	Profile Created:
First Name:	Last Name:
Enrollment Date:	
<hr/>	
STUDY:	
Study ID:	Condition:
Study Name:	Procedure:
Data sets:	Study Type:
Approval Date:	Start Date of Study:
<div>Search Clear</div>	

FIG. 11



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Open Enrollment Functions

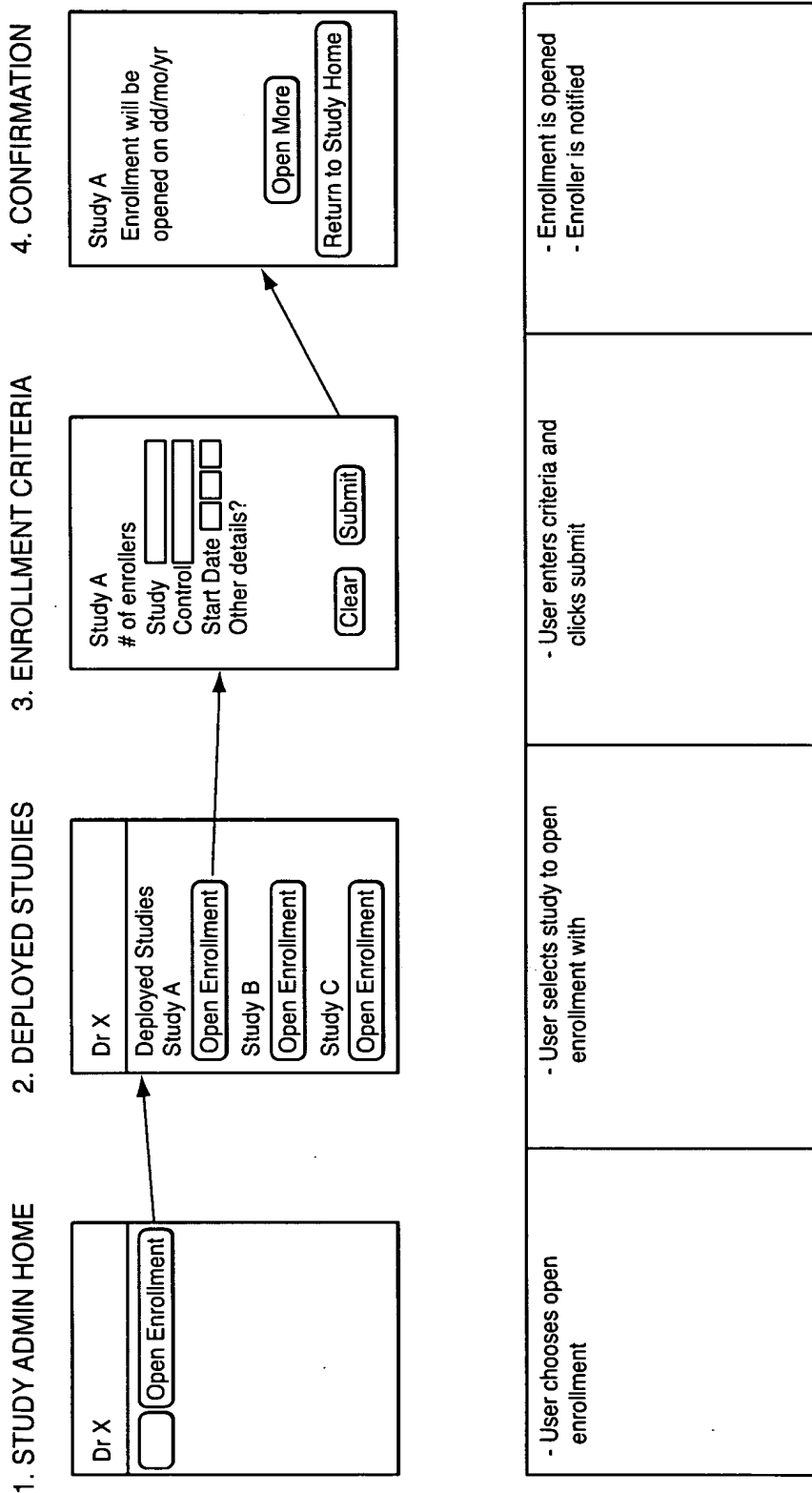
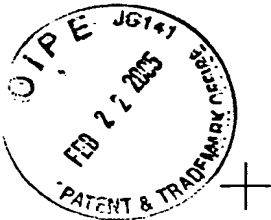


FIG. 12

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Close Enrollment Functions

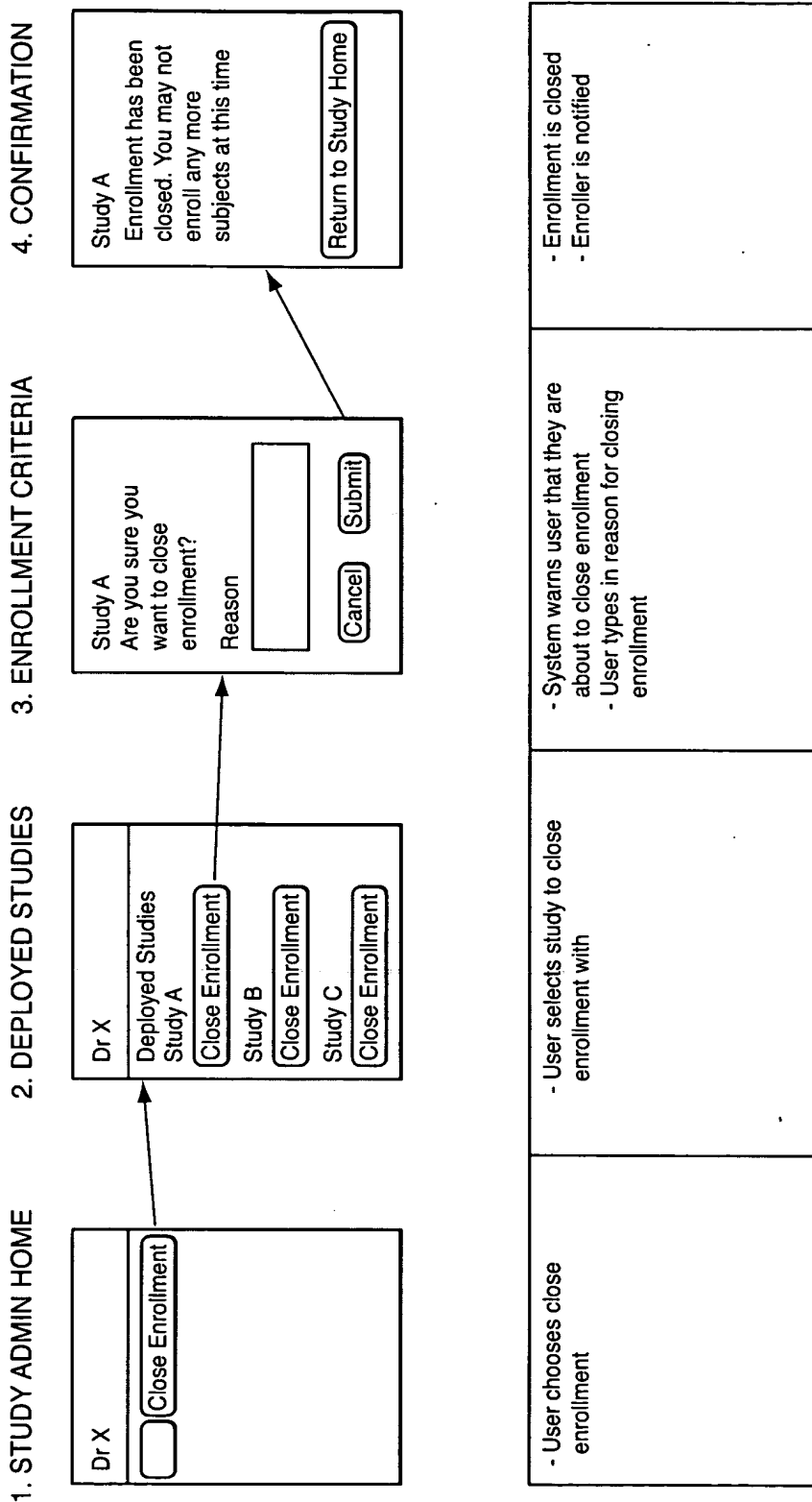
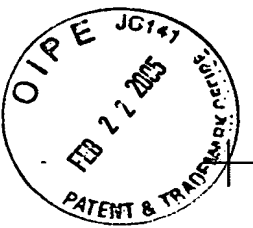


FIG. 13



Role Definition Function

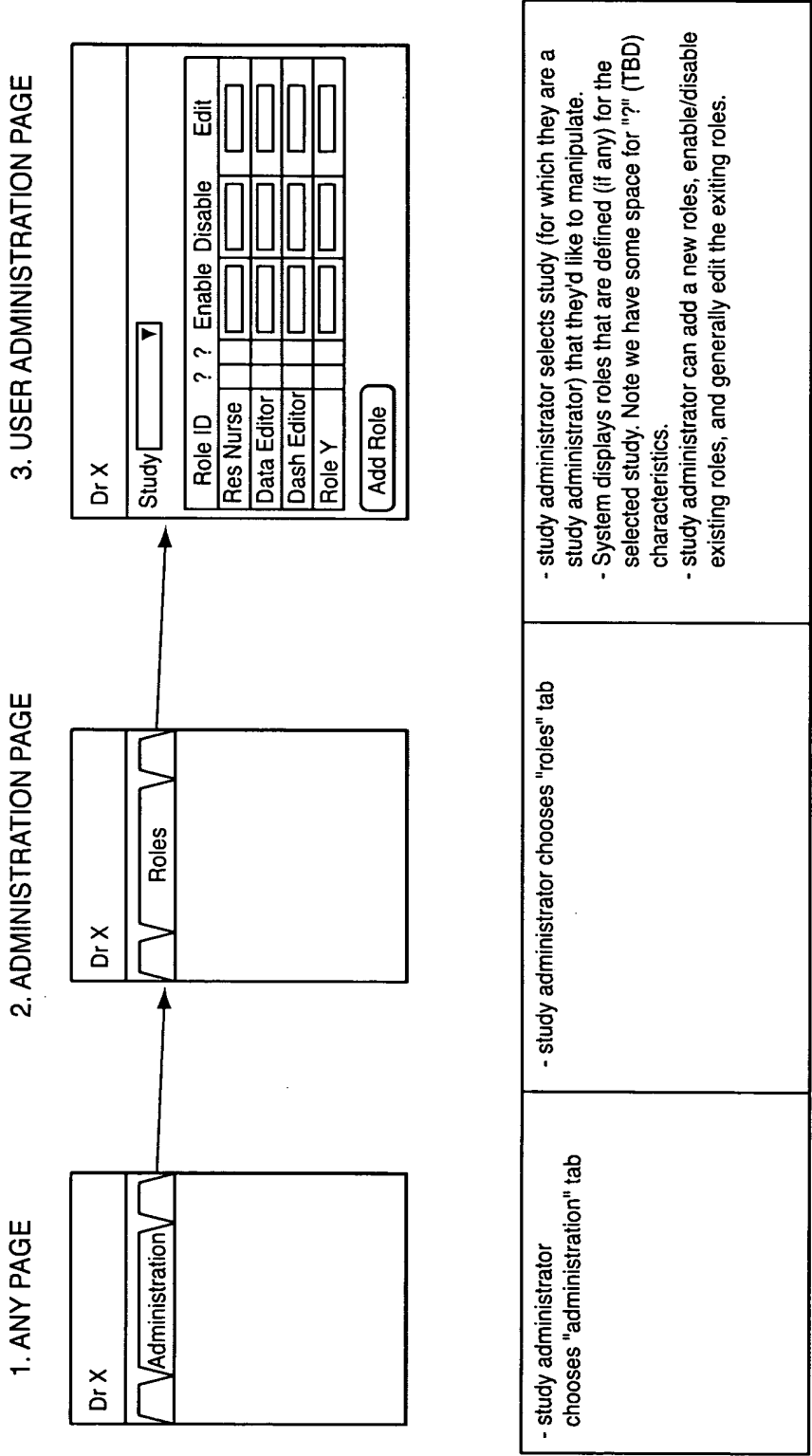
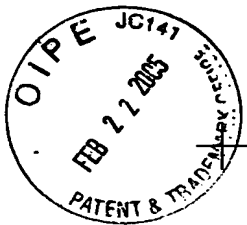


FIG. 14a

+



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Role Definition Function (Cont.)

5. CONFIRMATION PAGE

Dr X
Changes made to study have been committed
<div>Return to Administration Home</div> <div>Return to Roles</div>

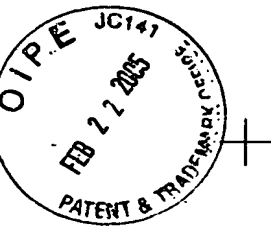
4. ROLE PAGE

Dr X
For Study XYZABC Role: Research Nurse 3
Capabilities: Enroll Subjects: <div>Assign</div> <div>Remove</div> Disenroll Subjects: <div>Assign</div> <div>Remove</div>
<div>Submit</div>

<ul style="list-style-type: none">- study administrator selected Add Role or edit an existing role from previous page or- when study administrator selects either Assign or Remove, the system refreshes the page to indicate updated information- the <i>fault line</i> simply indicates that there are lots of capabilities and we'll need to find a nice model to reflect them.- Move discrete data-oriented capabilities like Edit Data and Review Data capabilities have a sub-table for known data sets (and the ubiquitous freeform dataset (attachment, link, or block of text).	<ul style="list-style-type: none">- System confirms Role revision / creation
---	--

FIG. 14b

+



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Role Assignment Function

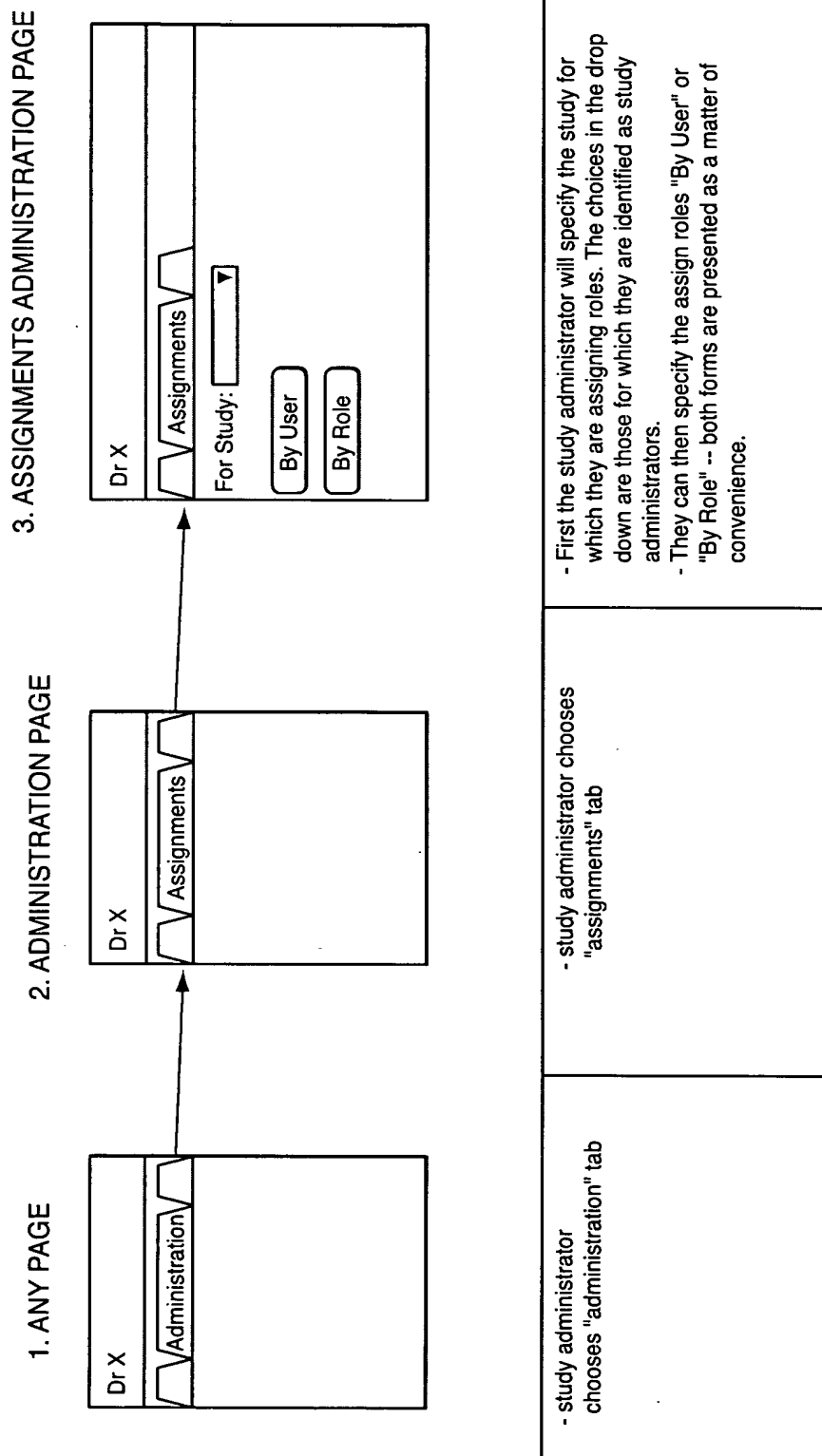


FIG. 15a

Role Assignment Function (Cont.)

4A. ROLE ASSIGNMENT BY USER PAGE OR 4B. ROLE ASSIGNMENT BY ROLE PAGE

Dr X

Assignments

For Study: XYZABC

Apply to User: ▼

Assigned Roles

Available Roles

Assign ▼

Remove ▲

Submit

Dr X

Assignments

For Study: XYZABC

Role: ▼

Users With Roles

Users Without Roles

Assign ▼

Remove ▲

Submit

Dr X

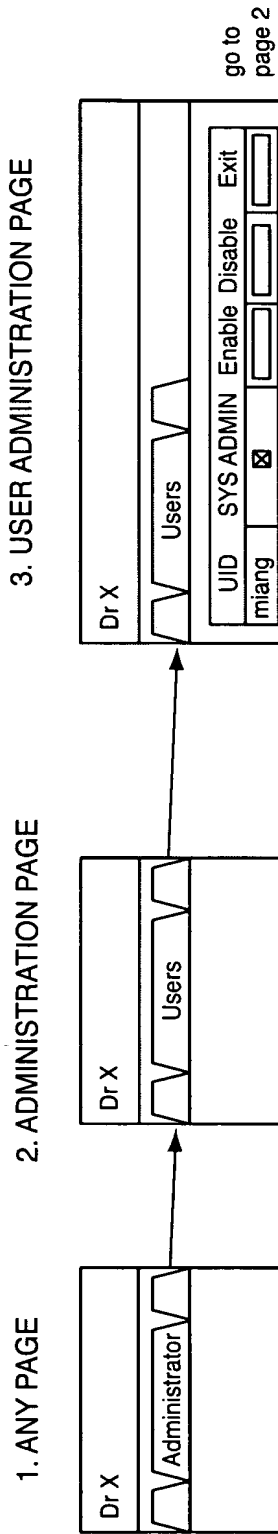
Changes to roles have been committed

Return to Roles

- View if study administrator selected "By User" - study administrator can Assign/Remove roles by clicking on the "Assign" and "Remove" buttons - System will refresh page when user Assigns/Removes Roles	- View if study administrator selected "By Role" - A study administrator can Assign/Remove roles by clicking on the "Assign" and "Remove" buttons (assigning users to the roles) - System will refresh page when user Assigns/Removes Roles	- System confirms Role assignments
--	---	------------------------------------

FIG. 15b

User Administration Function

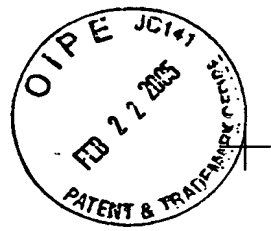


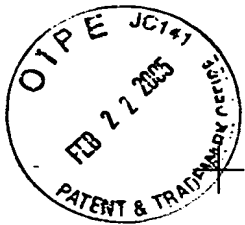
UID	SYS ADMIN	Enable	Disable	Exit
mian	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
rhatch	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
jones	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
smith	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

New User

<p>- User chooses "administration" tab</p>	<p>- User chooses "users" tab</p>	<p>- System displays users</p> <p>- User can:</p> <ul style="list-style-type: none"> + add a new user + enable/disable users +edit a user. (choosing edit will take the administrator to the next page).
--	-----------------------------------	---

FIG. 16a





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User Administration Function (Cont.)

4. USER PROFILE PAGE 5. CONFIRMATION PAGE

Dr X	
UID: <input type="text" value="ismith"/>	Contact Data: _____ _____ _____ _____
First Name: <input type="text"/>	
Last Name: <input type="text"/>	
Email: <input type="text"/>	
Is System Admin: <input checked="" type="checkbox"/>	Is Study Admin: <input checked="" type="checkbox"/>
Is Registrar: <input type="checkbox"/>	Studies: <input type="text" value="Study1"/> <input type="text" value="Study2"/> <input type="text" value="Study3"/>
<input type="button" value="Submit"/>	

Changes to UID ismith have been committed

- User credits various aspects of the user's profile. - Users clicks submit to commit changes	- System confirms the commit of changes to the user.
--	--

FIG. 16b

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Add/Edit Genetics Data Functions

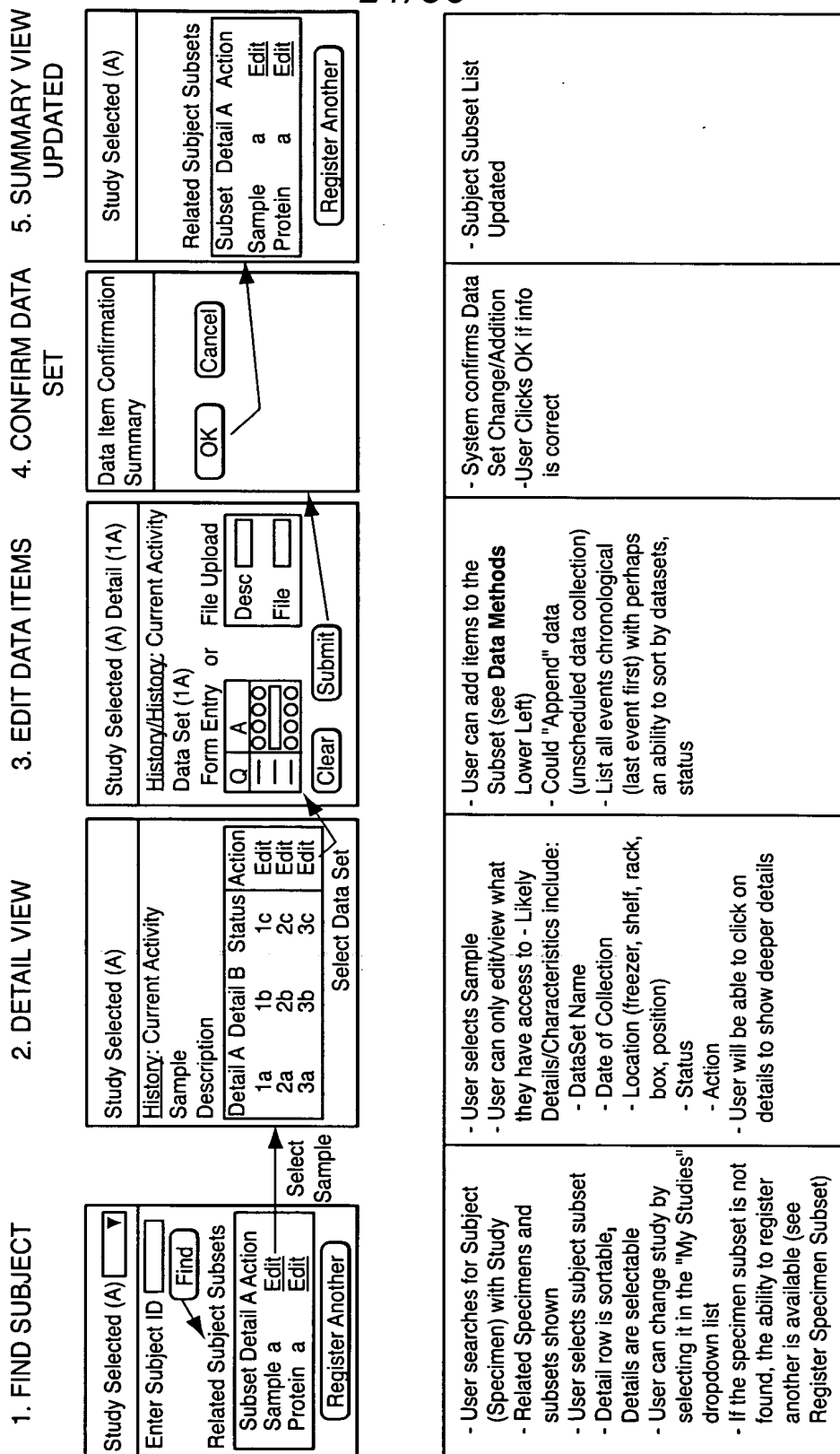
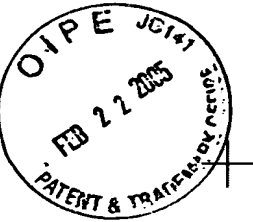
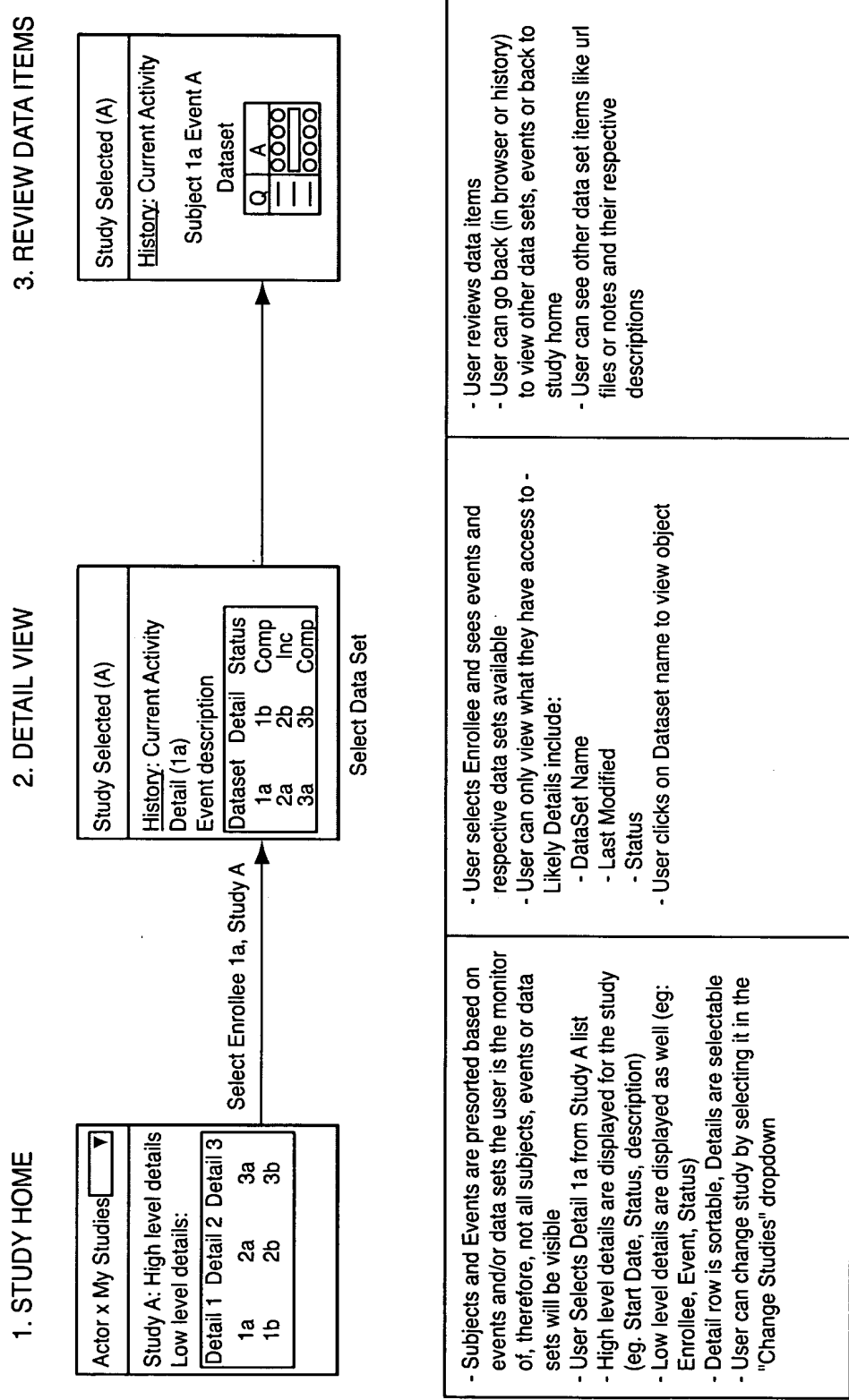
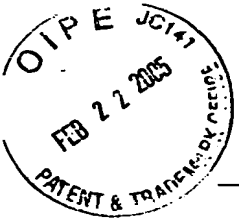


FIG. 19



Review Data Functions





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Approve Data Functions

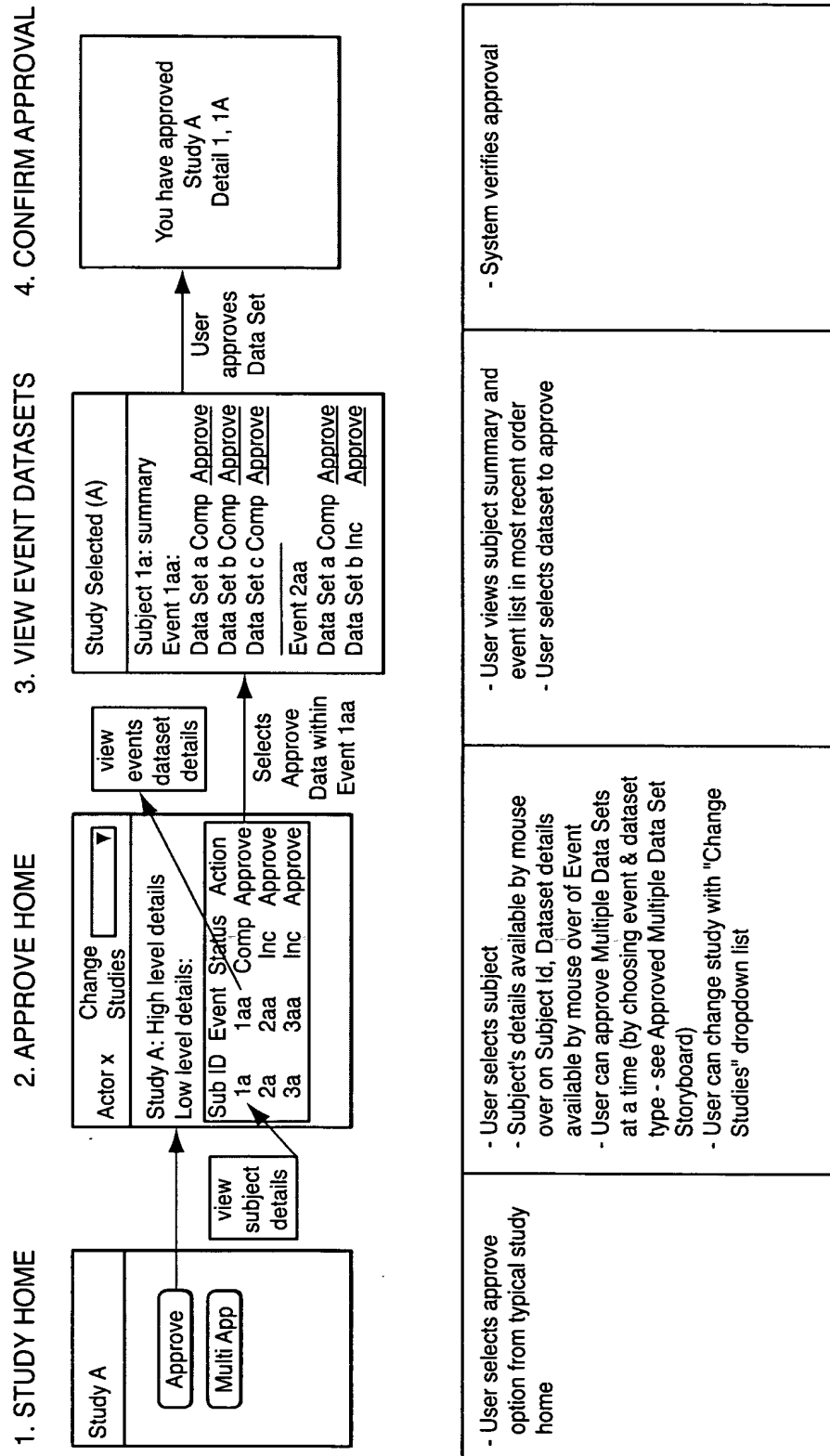
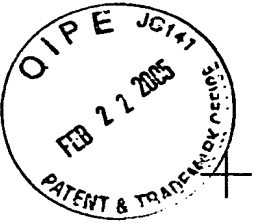


FIG. 21



Approve (freeze) Data Set Functions

1. TAILORED HOME PAGE

Actor x My Studies [dropdown]

Study A: High level details

Low level details:

Detail 1	Detail 2	Detail 3
1a	2a	3a
1b	2b	3b

[Approve] [Export]

View Details of Detail 1A

2. VIEW DETAILS

Study Selected (A)

History: Current Activity

Detail A	Detail B	Detail C
1a	1b	1c
2a	2b	2c

[Approve]

User approves Data Set

User approves Data Set

3. CONFIRM APPROVAL

You have approved Study A Detail 1, 1A

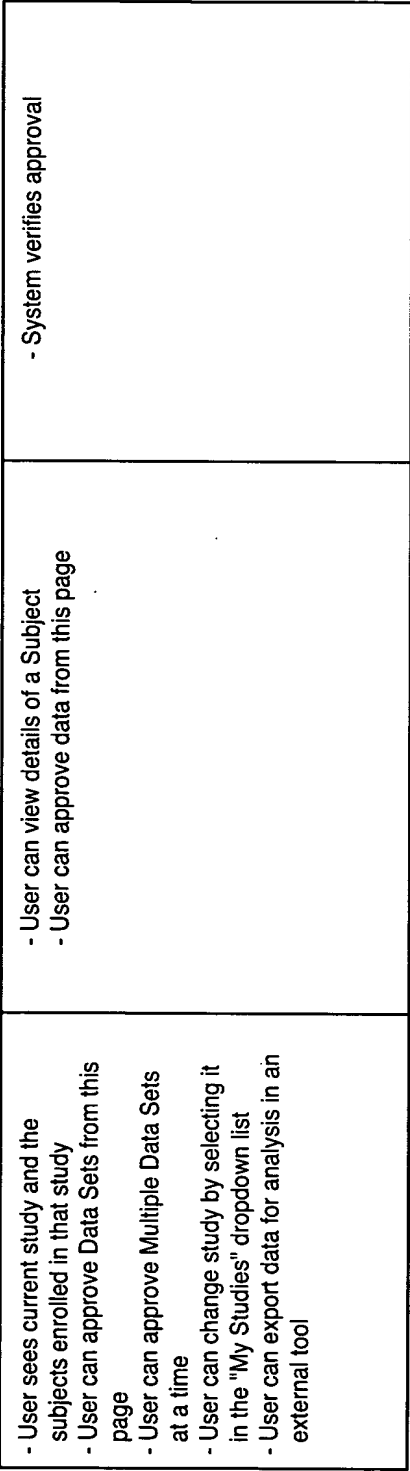
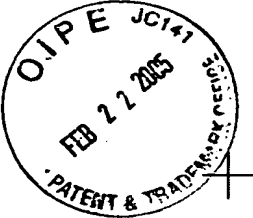
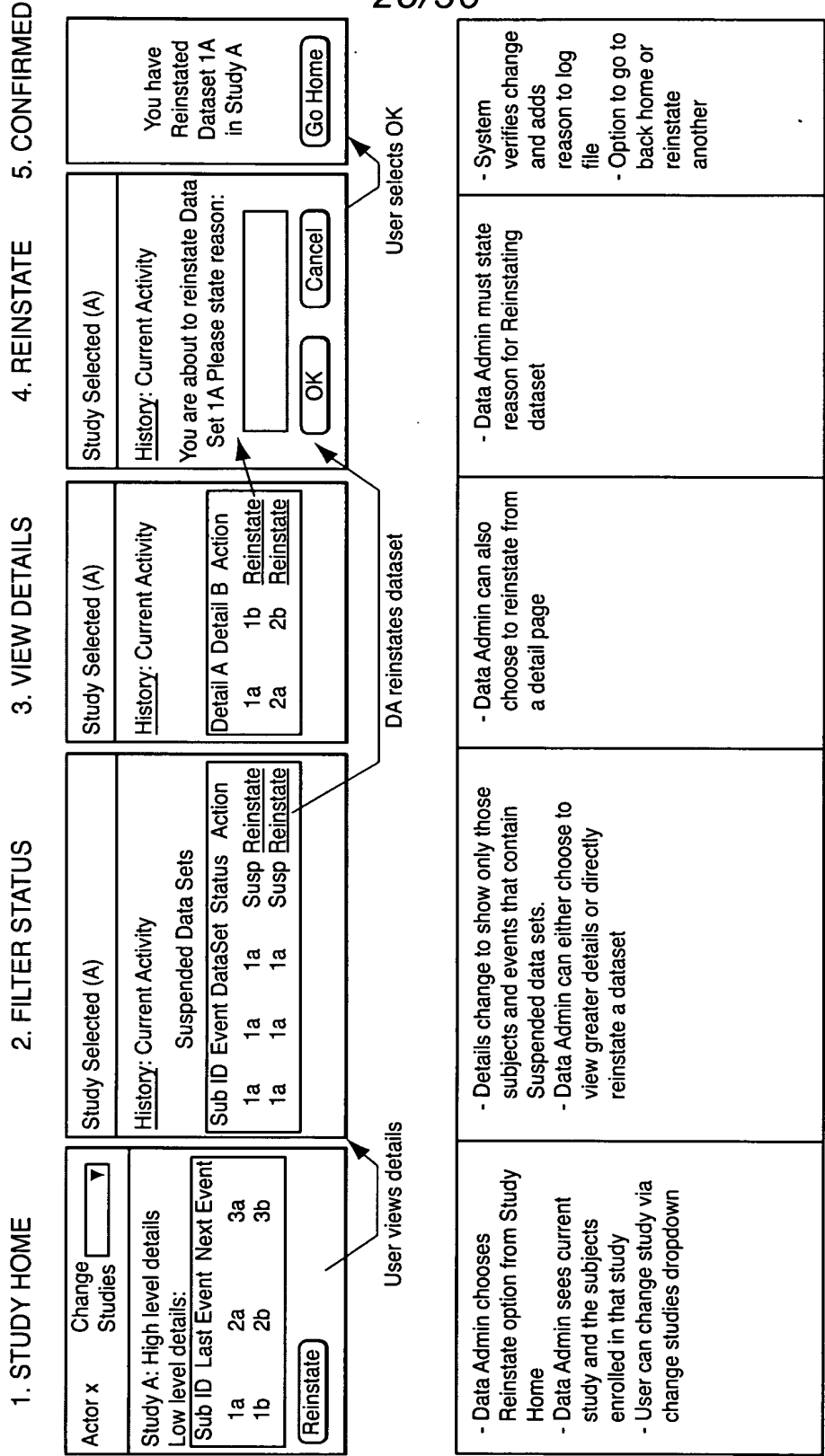


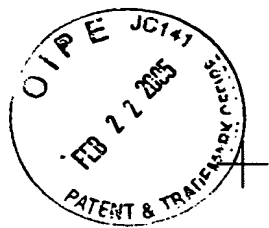
FIG. 22





Reinstate Function





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SCCTR

SPONSORED BY THE
ALBERTO VILAR CENTER

User: Robert Hotchkiss, MD

SCCTR Mail Preferences | Help | Logout

Search:

Last Name

Back To

--Select a Study--

SCCTR Mail Message Center

SCCTR Mail Home

Post Message

For:

Study:

Title:

Message:

Priority:

View Messages

To sort alerts, click on the column header that you wish to sort on.

Study:

Date	User	Title	Priority
09/30/2001	hotchkiss	Enrollment for Basal Joint Arthritis Closed	High
09/11/2001	twright	Subject 457342 is disenrolled for study	High
07/23/2001	larola	Subject 123442 is disenrolled for study	High
08/12/2001	hotchkiss	Collaborator Walter Reed data Set Editability Suspended	Normal
06/18/2001	hotchkiss	Subject 123442 is disenrolled for study	Alert
09/23/2001	twright	Enrollment Closed for Basal Joint Arthritis Study	Normal
09/11/2001	larola	Subject 123442 is disenrolled into study	Low
07/23/2001	hotchkiss	Collaborator TIGR data set editability has been Reinstated	Normal

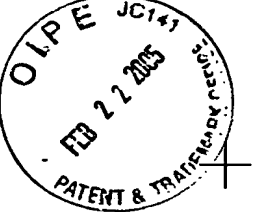
Sponsored by the
Alberto Vilar Center
for Research at the
Hospital for Special Surgery

Problems?
SCTR Administrator
John Doe

Legal Notices

FIG. 24

Application Serial No. 10/055,675
Amendment Dated February 17, 2005
Reply to Office Action Dated October 1, 2004
REPLACEMENT SHEET



SPONSORED BY THE
ALBERTO VILAR CENTER

SCTH

User: Robert Hotchkiss, MD

SCTH Mail Preferences | Help | Logout

Search:

Last Name

Study Home

Manage Subjects

Reports

Administration

Register

Study: 445599 Basal Joint Arthritis

Manage Subjects Home

Change Studies

View All Studies

Manage Subjects

Candidates

Find

Enroll

Enrolled

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

Sponsored by the
Alberto Vilar Center
for Research at the
Hospital for Special Surgery
Problems?
SCTR Administrator
John Doe
[Legal Notices](#)

Enrolled Subject View

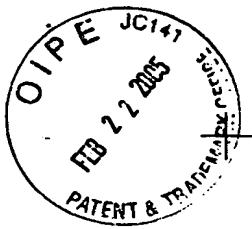
Subject ID	First Name	Last Name	Sex	Age	Last Event	Status	Last Event Date	Next Event
123456	Mary	Smith	F	22	Initial visit	Comp	09/11/2001	Surgery
123455	Brenda	Heidelberg	F	32	Initial visit	Inc	09/11/2001	Surgery
123454	Helga	Rothchild	F	48	Initial visit	Inc	09/11/2001	Surgery
123453	Donna	Donaldson	F	67	Surgery	App	09/19/2001	1-Mon Postop
123452	Flora	Dorfman	F	79	1-Mon Postop	Inc	09/11/2001	3-Mon Postop

Total number of enrollees: 27

Scheduled Event Status View

EVENT	DATA ENTRY STATUS			
	TBE	Incomplete	Complete	Approved
Initial Visit	18	22	5	3
Surgery	4	5	12	9
1-Mon Postop	12	12	3	2
3-Mon Postop	2	3	2	1
3-Mon Postop	3	0	0	0
1-Yr Postop	3	0	0	0
2-Yr Postop	3	0	0	0

FIG. 26



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SCTHR

SPONSORED BY THE
ALBERTO VILAR CENTER

User: Robert Hotchkiss, MD

SCTR Mail | Preferences | Help | Logout

Search:

Last Name

Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Subject View
Subject 123456

Change Studies

Manage Subjects

Candidates

Find

Enroll

Enrolled

View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

Sponsored by the
Alberto Vilar Center
for Research at the
Hospital for Special Surgery

Problems?

SCTR Administrator
John Doe

Legal Notices

General Characteristics

Sex: Female
Age: 20
Race: Caucasian
Height: 6'00
Weight: 125
Eye Color: Brown

Event List

Scheduled Events

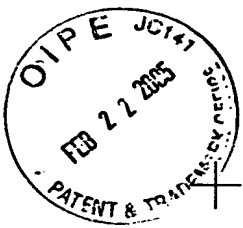
Event	Data Status	Last Modified
Initial Study Visit	Inc	04/08/1998
Surgery	Inc	04/10/1998
1-Mon Postop	TBE	---
3-Mon Postop	Comp	04/11/1998
3-Mon Postop	Comp	04/10/1999
1-Yr Postop	Inc	04/10/2000
2-Yr Postop	Comp	04/10/2001

Event Last Modified

Physical Exam 04/08/1998
Surgery 04/10/1998

FIG. 27

Application Serial No. 10/055,675
Amendment Dated February 17, 2005
Reply to Office Action Dated October 1, 2004
REPLACEMENT SHEET



SCCTR

SPONSORED BY THE
ALBERTO VILAR CENTER

User: Robert Hotchkiss, MD

Search:

Last Name

go

SCCTR Mail | Preferences | Help | Logout

Change Studies

View All Studies

go

Manage Subjects

Candidates

Find

Enroll

Enrolled View

Disenroll

Events

Choose

View Scheduled

View Status

Add Unscheduled

Data Sets

Choose

Edit

Approve

Retract Approval

Sponsored by the
Alberto Vilar Center
for Research at the
Hospital for Special Surgery
Problems?
SCTR Administrator
~~John Doe~~
Legal Notices

Manage Subjects

Study: 445599 Basal Joint Arthritis

Manage Subjects: Add Unscheduled Event Confirmed
Subject 123456

Add Unscheduled Event Confirmed

The Unscheduled Event Thumb Check-up has been successfully added.

Study: 445599 Basal Joint Arthritis

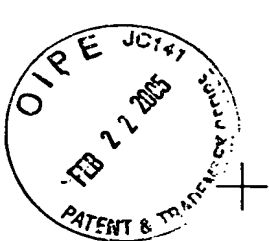
Subject ID: 123456

Return to Subject View

Return to Event View

FIG. 29





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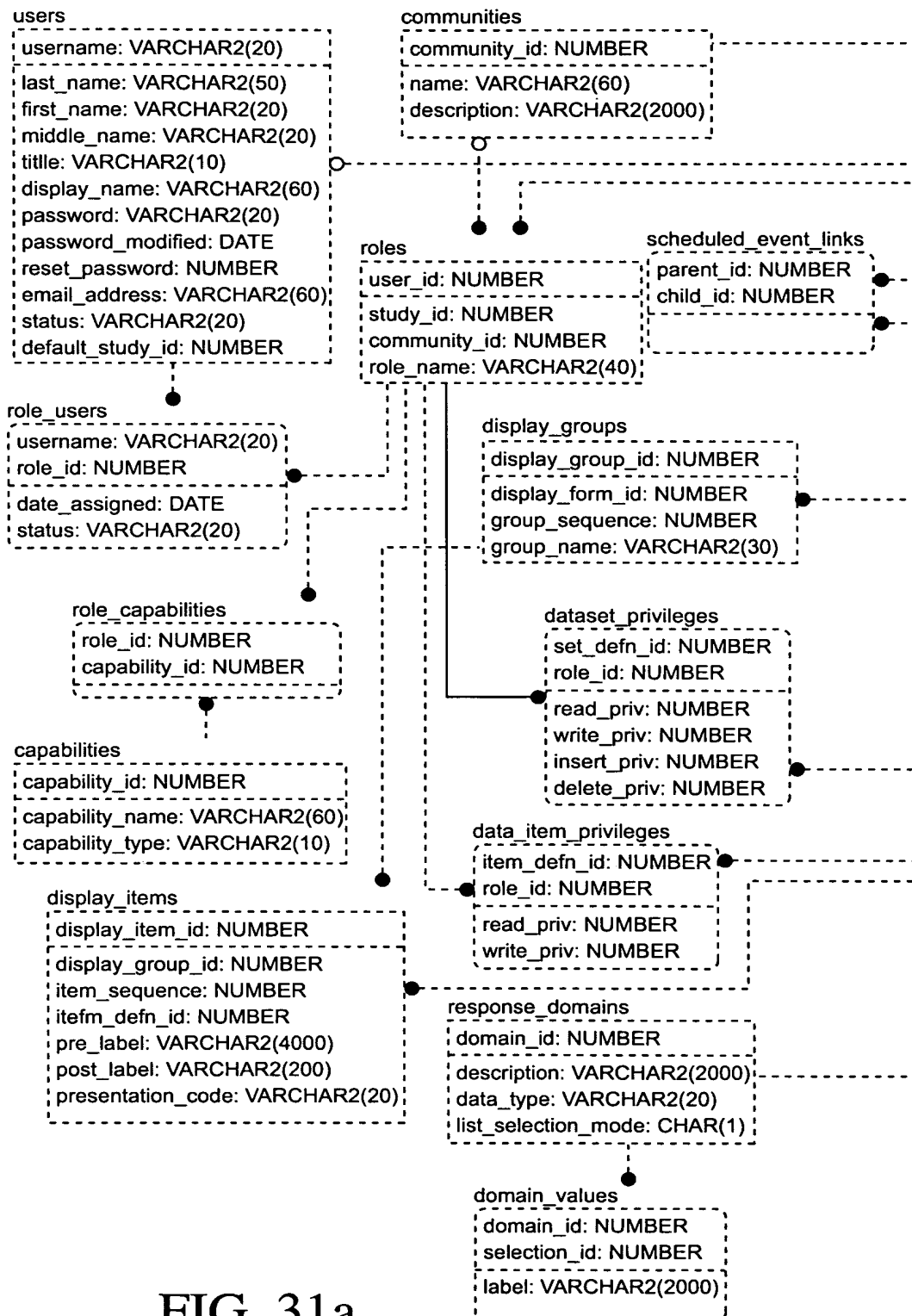


FIG. 31a



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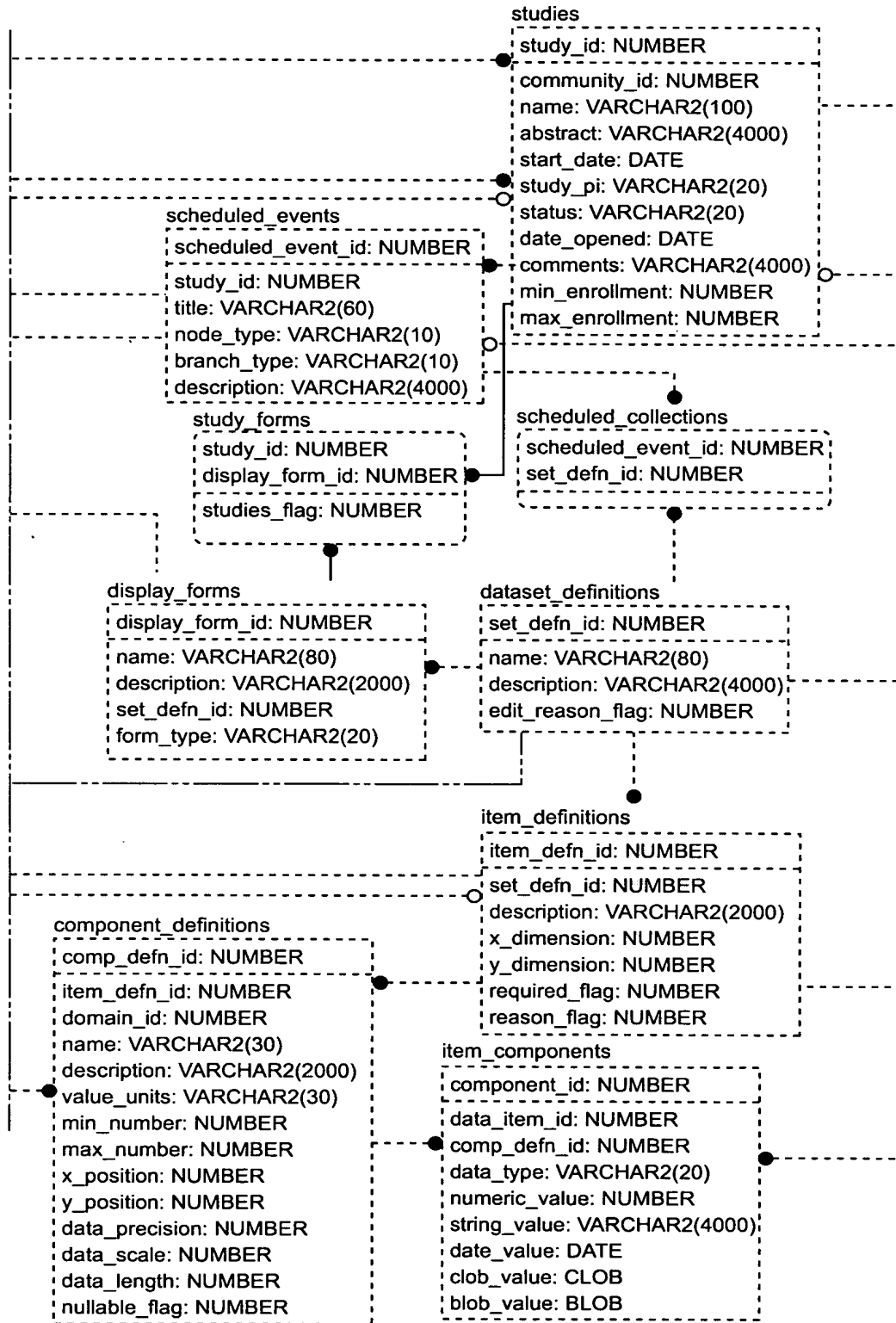
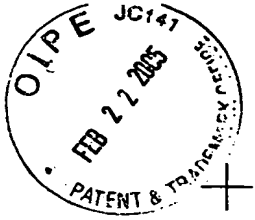


FIG. 31b



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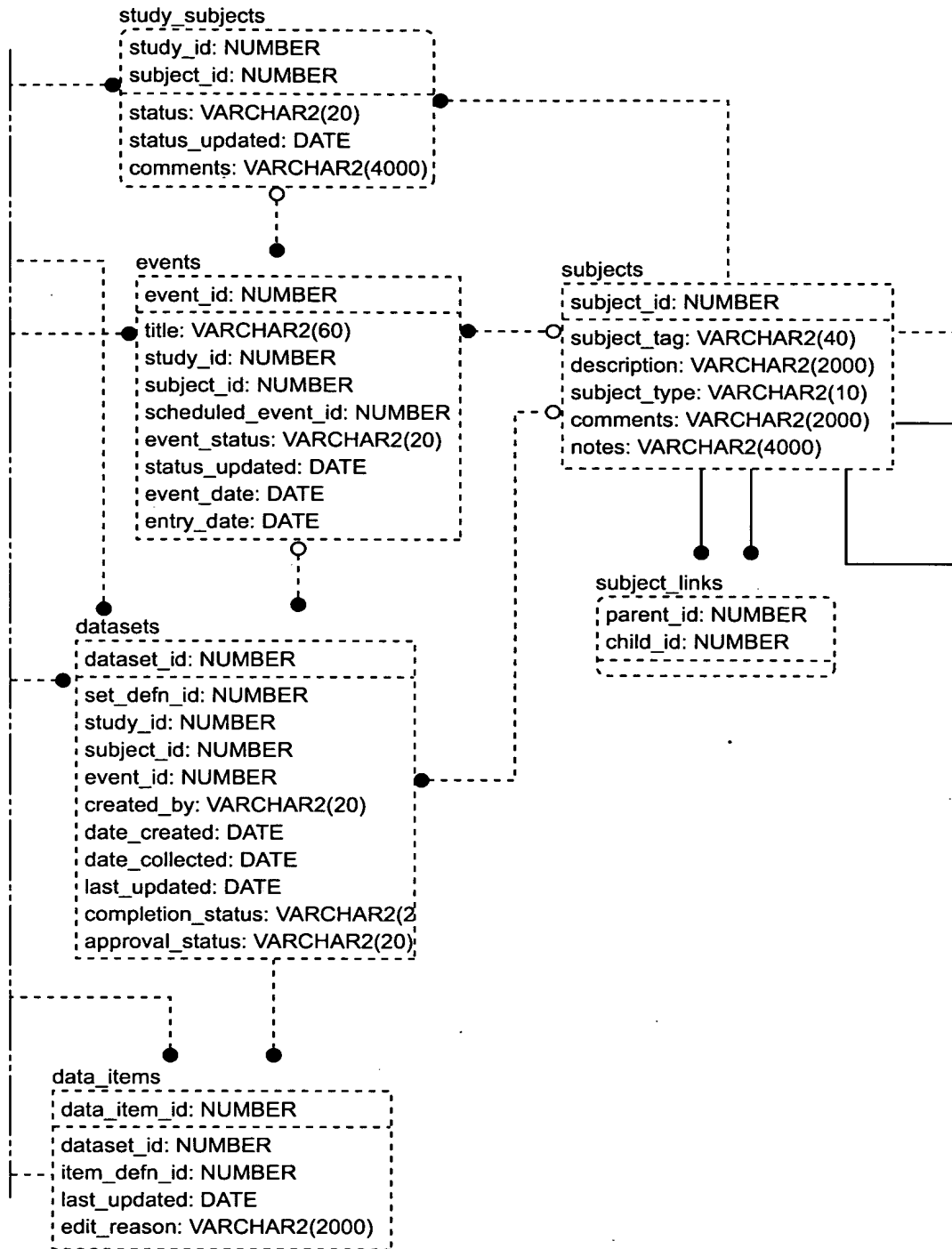
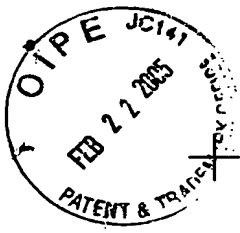


FIG. 31c





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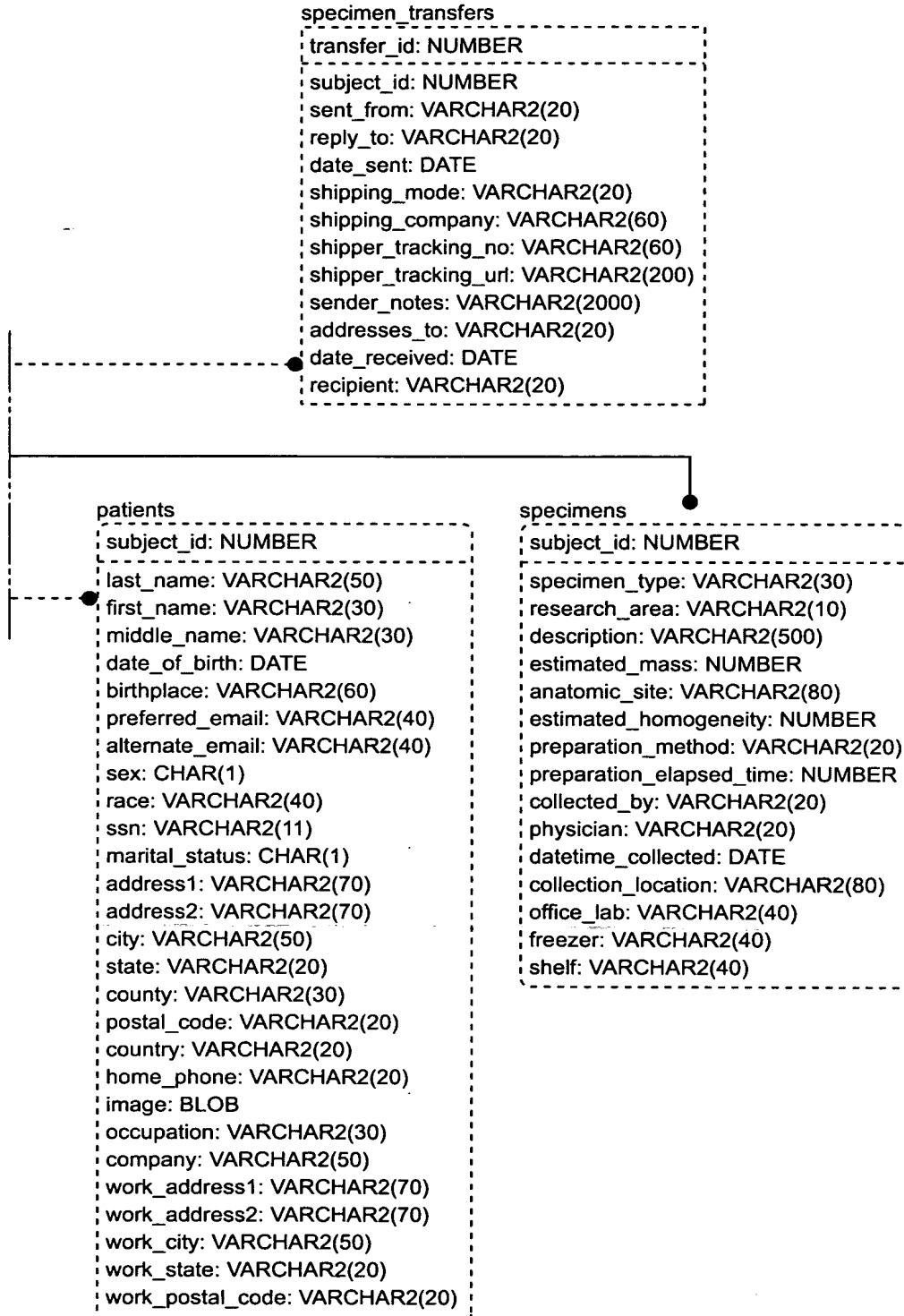


FIG. 31d

